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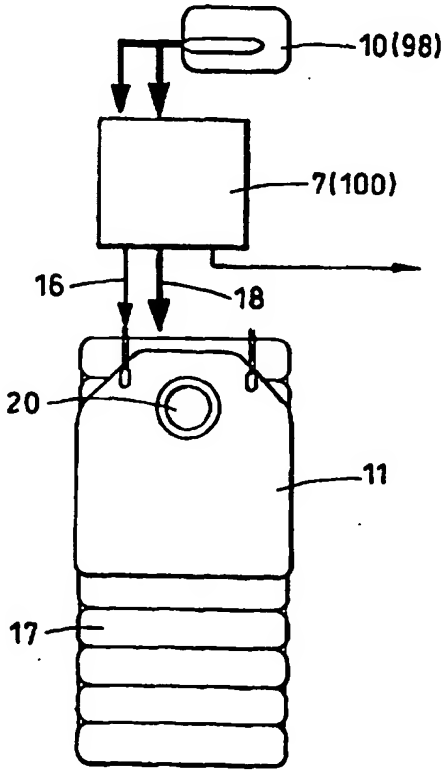
(54) Title: COOLING SYSTEM

(57) Abstract

A cooling system is disclosed for cooling a person in a supine position as part of a clinical treatement. The system includes an air blower (10 or 98), a heat exchanger (7 or 100), an inflatable mattress (17) and a cooling jacket or overlay (11, 200). Air from the blower is cooled by contact with the heat exchanger, passed through the jacket or overlay and through the mattress in order to rapidly cool the person so as to achieve mild hypothermia.



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COOLING SYSTEM

This invention relates to cooling systems for cooling a person in a supine position. There are circumstances in which it may be desirable to positively cool a patient as part of clinical treatment. For example, recent investigations have indicated that benefits may arise by subjecting patients who have suffered a stroke or cardiac arrest to mild hypothermia, e.g. a temperature in the range of 32 to 34°C for a period of more than about 1 hour after the cardiac arrest. This clinical procedure is described in the paper by Fritz Sterz et al in Journal of Neurological Anaestheology, Volume 8, No. 1, pages 88 to 96, published 1996.

It is, therefore, an object of the present invention to provide a method and equipment for carrying out such a clinical procedure, as well as for cooling patients for other purposes.

According to one aspect of the present invention, therefore, there is provided a method of cooling a person in a supine position on a support which comprises passing cooled air through a flexible jacket which underlies or overlays the person, said jacket preferably having apertures to allow escape of cooling air. Preferably, the jacket is adapted to overlay the person and to cover at least his torso. In an especially preferred form, the jacket or blanket substantially covers the person from head to foot.

The present invention includes a mattress which is associated with a heat exchanger, the heat exchanger being connectable to a source of cooling fluid such as water so that the patient may be cooled as required, by connecting the heat exchanger to a source of cooled liquid, such as a refrigerant.

According to a further feature of the present invention, therefore, there is provided a mattress having inflatable compartments for supporting a person thereon, and air supply means for supplying pressurised air to the mattress, said mattress having a heat exchanger associated therewith, through which said pressurised air can be

passed and said heat exchanger being connectable as required to a source of cooling fluid, such as a refrigeration circuit, whereby pressurised air can be cooled as required, and applied directly to the patient or to a jacket or blanket in contact with the patient.

Preferably, in such a mattress, the source of air comprises a pump unit having an outlet for connection to the inflatable compartments, and an outlet for connection to an inflatable cooling jacket or blanket.

The heat exchanger may be located in a housing physically attached to the mattress or to a bed on which the mattress is supported. Alternatively, the heat exchanger may be contained in a separate unit and connected to the mattress (and/or cooling jacket or blanket) by conduits, which are normally flexible.

The heat exchanger is conveniently supplied with cooling liquid, either by being incorporated in a refrigeration circuit in which the heat exchanger is on the expansion side, or fed with cooling fluid from a refrigeration system. In the latter case, the cooling fluid is generally water or an aqueous liquid such as brine, and is cooled by contact with the heat exchanger of a refrigeration circuit. This arrangement has the advantage that the cooling fluid circuit, such as water, provides a heat reservoir which irons out sharp fluctuations in temperature in the system. However, the former, more direct, cooling system works satisfactorily and has a quicker start up and will attain steady state more quickly. Preferably, a regulator valve is introduced into the refrigeration circuit and controls the flow of refrigerant fluid as required to maintain a desired temperature at the supporting surface of the mattress. This can be achieved, for example, by using a solenoid regulator hot gas by-pass valve in the refrigeration circuit, which is controlled by a digital PID controller connected to one or more temperature sensors at the exit end of the heat exchanger.

It is convenient to extract heat from an air stream by blowing air over the heat exchanger and feeding the pressurised, cold air to the mattress and also to the cooling

jacket or blanket. Normally, the air supplied to the mattress is intended to be sufficient to provide support for the patient as well as to provide the desired cooling effect. Where the same blower is used to supply air both to the mattress and jacket/blanket, the majority of the air will be directed to the mattress.

Some of the air supplied to the mattress will pass to atmosphere via exhaust valves in the mattress for controlling air pressures in the inflated compartments or sacs of the mattress. Other quantities of air will escape via stitch holes in the surface of the mattress and form air streams which cool the patient by passing over his skin. Heat will also be abstracted from the patient by conduction through the surface of the mattress and by cooling air emitted from apertures in the cooling jacket or blanket.

It may be necessary to provide means to confine the patient to prevent shivering.

In the operation of the patient cooling system of the invention, the objective is to effect moderate to mild hypothermia. i.e. a body temperature of about 32-34°C. It is found that this can be achieved with the mattress and jacket/blanket of this invention using an air input temperature to the apparatus of about 1-3°C, preferably about 2°C. The mattress surface temperature should be less than 10°C, preferably about 5~10°C. Studies have indicated that clinical benefits are obtained in terms of reduction in brain damage if the temperature of the patient who has suffered cardiac arrest is reduced to a temperature in the range of 32-34°C within a few hours, preferably within 2 to 4 hours, of restoration of spontaneous circulation (ROSC). Hypothermia treatment needs to be started quickly after ROSC. e.g. within about 15 minutes.

Various embodiments of the present invention will be apparent from the accompanying drawings, in which:-

Figure 1 is a schematic illustration of a patient cooling system in accordance with the invention;

Figure 1A is a schematic illustration of an alternative system;

Figure 2 is a schematic representation of the application of the system of Figure or 1A to a cooling jacket;

Figure 3 is a view in elevation showing the cooling and blower pump unit;

Figure 3A illustrates a unit for housing a cooling system of the kind shown in Figure 1A with a blower pump unit;

Figure 4 is a plan view of a cooling jacket of the kind shown in Figure 2;

Figure 5 is a view of the jacket shown in Figure 4 in the direction of the arrow X in Figure 4, and

Figure 6 shows a modified cooling system in accordance with the invention.

Referring to the accompanying drawings, and in particular to Figure 1, in one form, the cooling system essentially comprises a refrigeration unit 1, comprising a compressor 2, a condenser 3 and an evaporation coil 4, through which the refrigerant is circulated. Water is circulated through the evaporation coil and the cooled water is circulated through pipes 5 and 6, to a heat exchanger 7. Air is passed through the heat exchanger 7 from a pump (not shown) as indicated schematically by the arrow 8 and the cooled air is then passed as indicated by the arrow 9 to the mattress.

Referring to Figure 1A, this shows an alternative system for providing a stream of controlled cooling air. A heat exchanger 100 has an inlet 101 for air from a blower 98 and an outlet 102 for a stream of cooled air which is connected to a flexible conduit 16, for connection to a mattress and cooling jacket, e.g. as shown in Figure 2. Heat exchanger 100 is connected directly to a refrigeration circuit which includes a compressor 103 and a condenser 104 and an expansion valve 105 and a by-pass valve 106. The by-pass valve is controlled by control means 107 which is linked to a thermistor connected to the refrigerant circuit at the exit from the heat exchanger, such that, e.g. a fall in temperature at the heat exchanger exit will signal the by-pass valve to

open, reducing the system cooling capacity. The valve, which is preferably a solenoid valve may be signalled to cycle on and off in response to temperature sensed at the heat exchanger exit. The valve 106 which is preferably a solenoid valve, may be signalled to cycle on and off in response to temperature sensed at the heat exchanger outlet. Where the mattress is of the low air loss type and individual air supply conduits are connected to different sections of the bed, e.g. the head, torso, seat and foot sections, in order to maintain air pressures appropriate for each part of the body, it may be desired to control the volume of air flowing through each section. Adjustment and control of the rate of air flow on the sections may be used to maintain each section at a desired target temperature.

A cooling system of the kind shown in Figure 1A may be housed in a blower/cooling unit as shown in Figure 3A. This shows a unit 110 in which the refrigeration unit comprises a compressor 103 and heat exchanger 100 are housed in the lower part and a blower 98 and air valves 114 for controlling the flow of cooled air to the mattress and blanket/jacket are located. Thermocouples may be provided at various positions on the mattress, e.g. spaced at intervals from the head to the foot and connected to the blower 98 or the air valves 114. A control panel 115 is mounted on the front of the unit 110 and includes the controls and instruments indicated. The refrigeration and blower are thus combined in a single unit and flexible hoses (not shown) connect the unit to the mattress and blanket. The control panel may report temperatures recorded at the mattress support surface and may include an indication of the patient's core temperature.

The air system is shown in Figure 2 which illustrates the connection of the pump unit 10 or 98 with the heat exchanger 7 or 100 and then to a cooling jacket 11. The pump unit comprises an air pump or compressor incorporating means for passing pressurised air through a tube, into the heat exchanger. The air pump 10 may include

pressure regulating controls, including means for circulating a pulsating pressure flow to the heat exchanger. The heat exchanger and air cooling unit may include a thermostat 13, low temperature warning light 14 and water indicator level 15, indicating the amount of water in the reservoir. The use of a water reservoir irons out fluctuations in the temperature of the cooling air stream.

After passing through the heat exchanger, the air stream flows into the cooling jacket 11 via the line 16. The cooling jacket may include flow and return pipes 32 and 33 (Figures 4 and 5) and/or include apertures (not shown) in the cooling jacket which is preferably directed onto the patient's skin in order to effect cooling by convection and conduction.

Figure 6 shows a modified system comprising a cooling unit 110 (e.g. such as shown in Figure 3A), connected to an inflatable low air loss mattress 17 and an inflatable overblanket 200. Separate flexible conduits 16 and 18 are provided to supply cooled air from the cooling unit to the mattress and overblanket, respectively. As shown in Figure 6, the cooled air is supplied to the foot end of the overblanket 200. It will be appreciated that the supply 16 to the mattress may consist of separate conduits to different groups of air sacs in the mattress, each conduit supplying air at a pressure appropriate for the respective part of the patient's body.

As shown in Figure 2 and 6, the cooling jacket 11 or overblanket 200 is preferably placed on top of a mattress 17 which may be of the inflatable type. Preferred mattresses are those of the so-called low-air-loss type, in which air is circulated through the mattress and the surface of the individual sacs or compartments are provided with a moisture vapour permeable material, so that moisture produced by the patient flows into the sacs and is carried away in the air stream. Inflatable mattress supports of this kind are described in US Patent No. 4,525,885, EPA 0034954 and EPA 0260087. The mattress may alternatively be designed to provide

pulsation therapy to the patient by cyclically varying pressures to the mattress, e.g. as described in US Patent No. 5396671.

In order to increase the rate of conduction of heat from the patient, the cooled air from the heat exchanger 7 or 100 may also be fed into the cushions of the mattress, thereby cooling the patient from below as well as above. The pump unit 10 or 98 may be provided with additional air outlets which by-pass the cooling unit if cooling from below is not required. Also, the pump unit may include pressure regulating features so that the individual cushions or groups of cushions in the mattress can be pressurised to a desired pressure, so as provide support for the patient over the maximum skin area.

Figures 4 and 5 show the construction of the cooling jacket in more detail. As can be seen from Figures 2 and 4, the jacket extends across the width of the mattress, and has an area which is designed to cover the torso, upper arms and head of the patient. The patient's nose and mouth is accessible through the aperture 20 so that a ventilation tube and other intensive care devices can be applied to the patient through this aperture.

The extreme edges of the jacket are provided with buckles and straps 21, 22 and 23, which can be passed around the mattress and the patient so as to hold the jacket in close contact with him.

The jacket comprises upper and lower layers of material which are air-impermeable, the two layers being welded at their edges so that the jacket forms an inflatable pad. Preferably, the upper and lower layers are welded together at intervals as shown at 30 so as to create a quilted effect.

Although not shown in the drawing, the lower layer 31 may be formed with a number of a small, e.g. pinhole-like apertures through which inflation air may escape so as to produce a stream of cooling air flowing over the patient's body.

One type of cooling jacket which can be employed for the purposes of the invention comprises a disposable paper jacket. This can be manufactured from the kind of paper used to make paper towels or operating theatre gowns and hats. The jacket will be formed with an inner and outer layer and include punched holes to permit the cooling air to escape. Because the paper jacket is light, a large air flow is achieved at low inflation pressure.

In another embodiment, the mattress may have associated with it a heat exchanger, e.g. connected below the mattress or connected to the pump unit 10 or 98. In normal use, this heat exchanger may not function but may be connected into the air supply system to the mattress. Also, the pump unit may include a port which can opened to supply a separate air stream, e.g. to a cooling jacket. When cooling is required, a separate cooling unit can be supplied which has connections to the heat exchanger. The cooling unit may include a compressor, condenser and evaporator coil, together with a reservoir for water which is connectable to the heat exchanger.

In general, the source of coolant will be a refrigeration system operated using a compressor and a vaporisable refrigerant. However, other refrigerating systems can be employed such as thermoelectric coolers, which function by means of the Peltier effect. These have the advantage that they can easily be operated by a D.C. electrical supply.

CLAIMS:-

1. A method of cooling a person on a support which comprises passing cooled air through a flexible jacket or blanket which underlies or overlays the person, said jacket having apertures to allow escape of cooling air.

2. A method according to claim 1 wherein said jacket is adapted to overlay the person so as to cover at least the torso of the person.

3. A method of cooling a person in a supine position on an inflatable mattress which comprises passing cooled air through said mattress and through an inflatable blanket having apertures to allow escape of cooling air.

4. A method as claimed in claim 3 wherein the inflatable mattress has apertures allowing cooling air to escape and directly cool the person.

5. A mattress having inflatable compartments for supporting a person, air supply means for supplying pressurised air to the mattress, said mattress having a heat exchanger associated therewith, through which said pressurised air can be passed to cool it, and said heat exchanger being connectable as required to a source of cool fluid whereby said pressurised air can be cooled as required.

6. A mattress as claimed in claim 5 wherein the heat exchanger is connected to a refrigeration circuit, said circuit including a regulator valve arranged to control flow of refrigeration fluid to the heat exchanger in dependence on temperature sensing means in the mattress or at its surface.

7. A mattress as claimed in claim 5 wherein the heat exchanger is connected to a circuit through which a cooled liquid is circulated, said circuit being associated with a second heat exchanger which is connected to a refrigeration circuit.

8. A mattress according to claim 5 wherein the source of air comprises a pump unit having an outlet for connection to the compartment, and an outlet for connection to an inflatable cooling jacket or blanket.

9. A mattress according to claim 8 wherein the jacket or blanket is designed to overlay the patient.

10. A mattress as claimed in claim 8 or 9 wherein said pump unit includes an outlet for connection to the jacket or blanket and an outlet for connection to said mattress.

11. A mattress as claimed in claim 10 wherein the mattress comprises a low air loss bed.

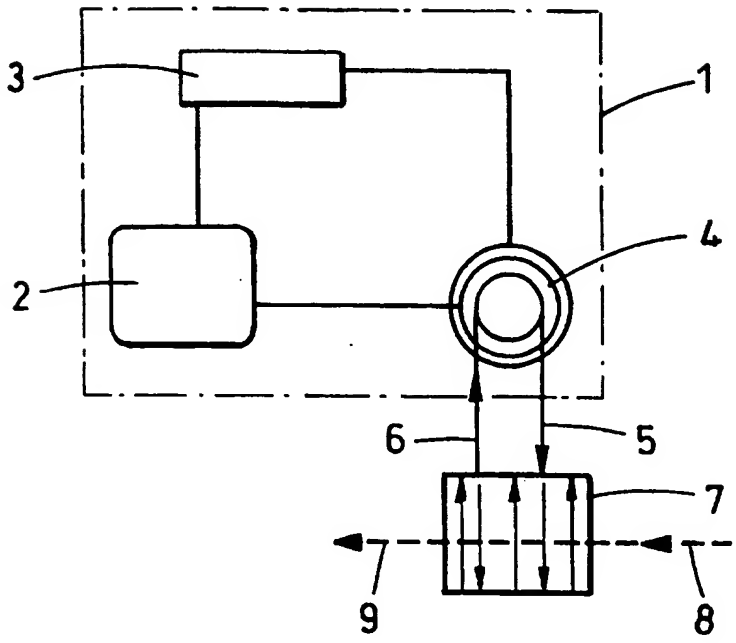


Fig. 1

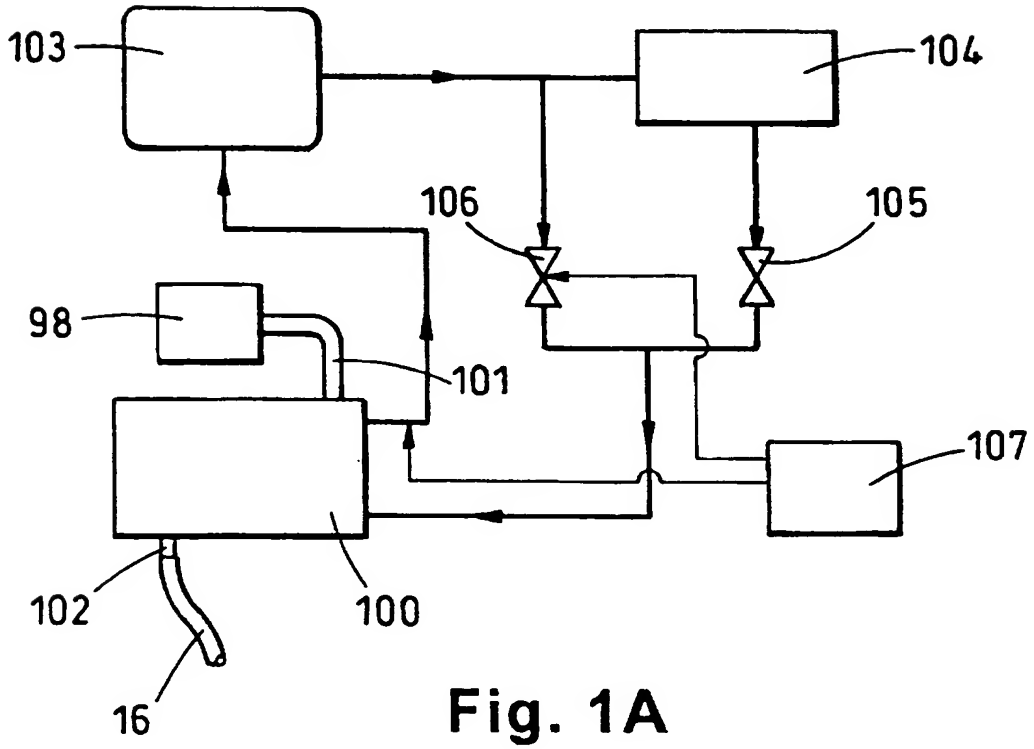


Fig. 1A

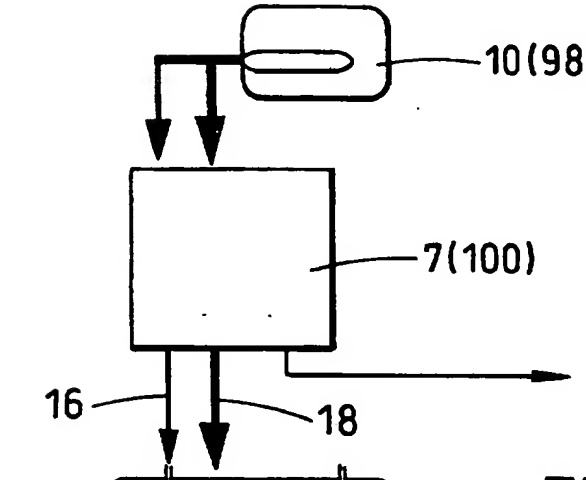
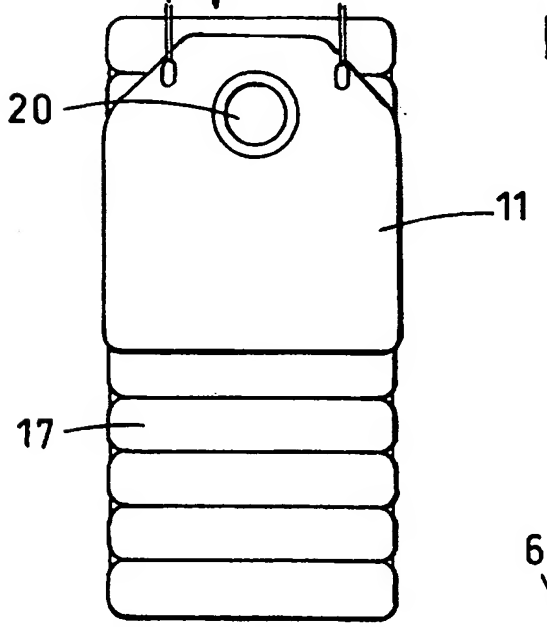


Fig. 2



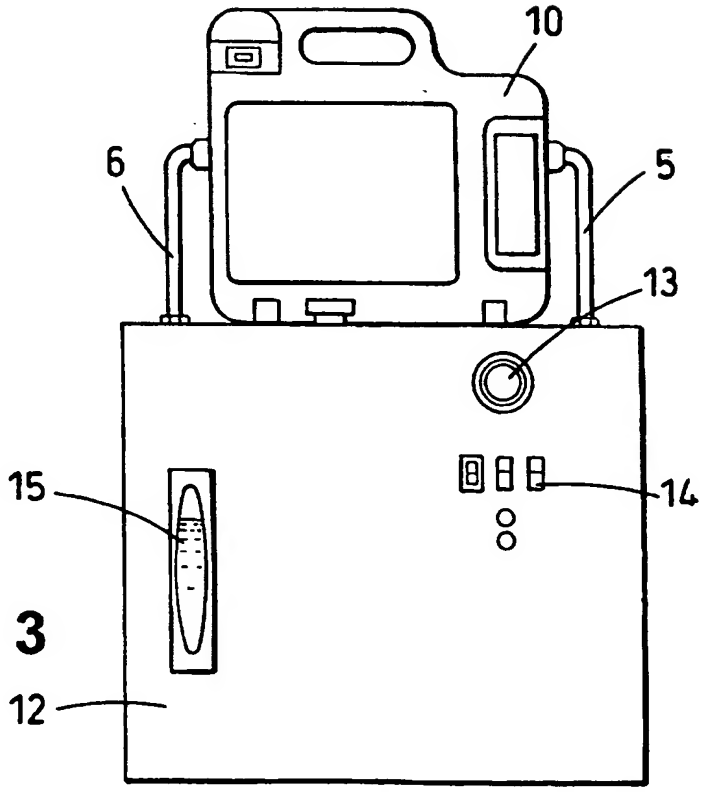


Fig. 3

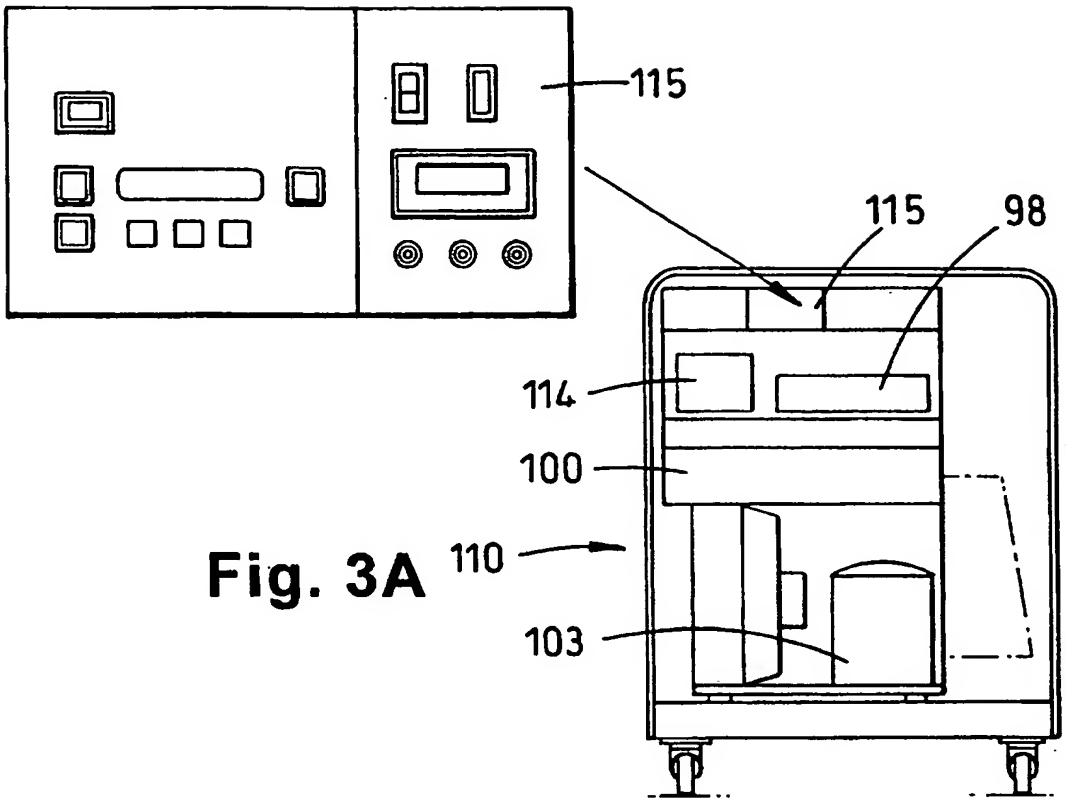


Fig. 3A

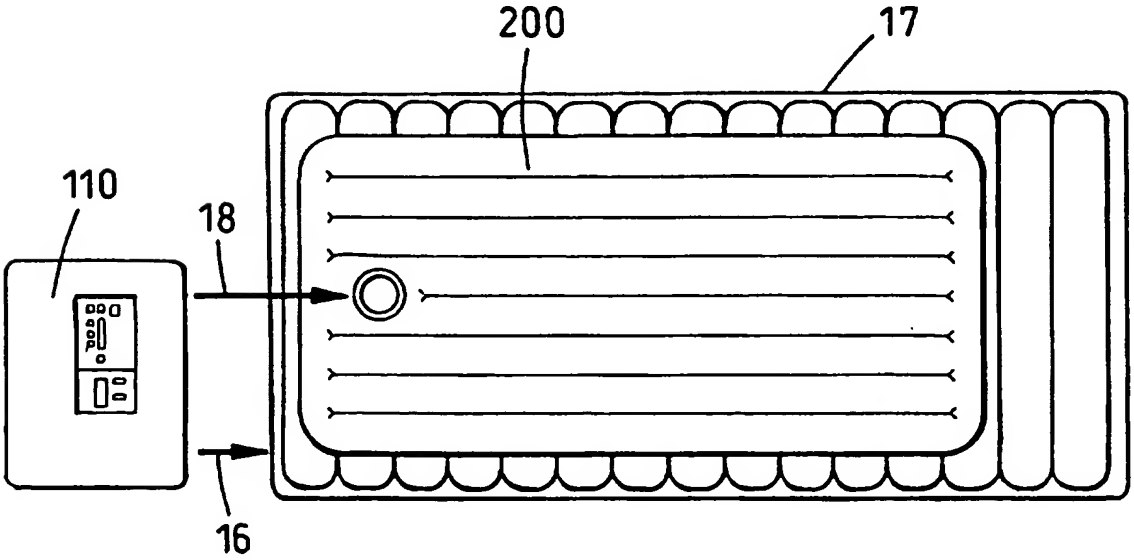


Fig. 6

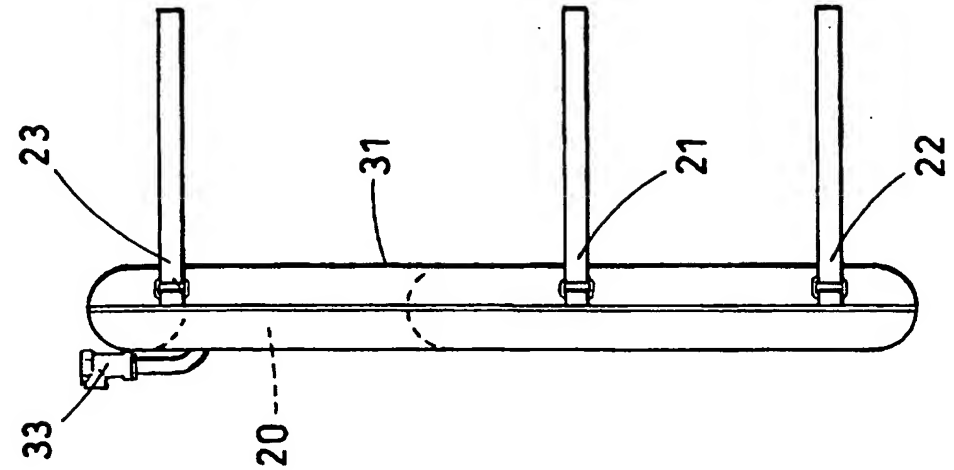


Fig. 5

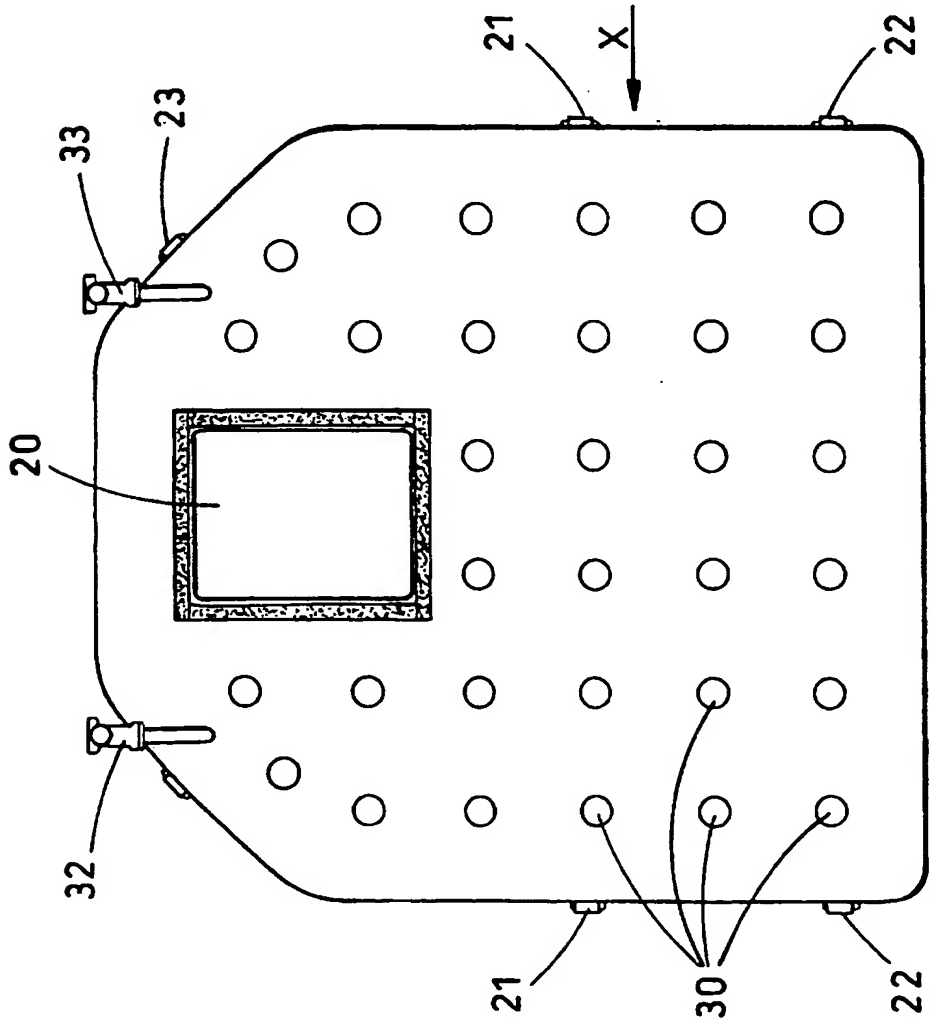


Fig. 4

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 97/01344

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F7/10 A47C21/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F A47C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4 638 519 A (HESS) 27 January 1987 see column 6, line 34 - line 36 see column 7, line 3 - line 6	5-11
Y	WO 95 10211 A (CHOI) 20 April 1995 see claim 1	5-11
A	US 4 660 388 A (GREENE,JR) 28 April 1987 see column 2, line 48 - line 56 see column 3, line 20 - line 23	5,7-10
A	US 4 170 998 A (SAUDER) 16 October 1979 see column 3, line 44 - line 67	6
A	US 5 081 339 A (STINE) 14 January 1992 see column 5, line 5 - line 25	6

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"&" document member of the same patent family

1

Date of the actual completion of the international search	Date of mailing of the international search report
6 October 1997	23. 10. 97

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 97/01344

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	GB 2 263 872 A (SI INDUSTRIES LTD) 11 August 1993 see page 7, line 33 - page 8, line 15 -----	6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB 97/01344

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 1-4
because they relate to subject matter not required to be searched by this Authority, namely:

pct rule 39.1(iv) treatment method

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/GB 97/01344

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COOLING SYSTEM

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Inventor: HEATON KEITH PATRICK (GB)
Applicant: KCI MEDICAL LTD (GB); HEATON KEITH PATRICK (GB)
Classification:
- international: A61F7/10; A47C21/04
- european: A47C21/04B; A61F7/10
Application number: WO1997GB01344 19970516
Priority number(s): GB19960010233 19960516

Also published as:

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US6730115 (B1)
GB2313549 (A)
EP0898473 (B1)
DE69728261T (T2)
DE69728261D (T2)
CA2254999 (C)

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Abstract of **WO9742919**

A cooling system is disclosed for cooling a person in a supine position as part of a clinical treatement. The system includes an air blower (10 or 98), a heat exchanger (7 or 100), an inflatable mattress (17) and a cooling jacket or overlay (11, 200). Air from the blower is cooled by contact with the heat exchanger, passed through the jacket or overlay and through the mattress in order to rapidly cool the person so as to achieve mild hypothermia.